REMARKS

Applicant respectfully requests reconsideration. Claims 28, 31-35 and 37-47 were previously pending in this application. Claim 28 is amended herein. As a result, claims 28, 31-35 and 37-47 are still pending for examination with claim 28 being an independent claim. No new matter has been added.

Withdrawn Rejections

Applicants acknowledge and thank the examiner for the indication that several prior rejections have been withdrawn.

Rejection Under 35 U.S.C. 112

Claims 28, 31-33, 35, 37, 39, 40 and 42-47 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

The office action asserts that primary immune system deficiencies have an absence or reduced number of T cells or mature B cells and that one would not expect a CpG ODN to work in the absence of functioning B and T cells. The data in the specification not only establishes that CpG oligonucleotides are able to activate B cells but that they induce expression of IL-6, IL-12 and IFN-gamma as well as stimulate NK cell activity. A conclusion that CpG ODN would not be useful in the treatment of a disease that has reduced B cells is not sufficient to support a lack of enablement. The CpG oligonucleotides would still be expected to stimulate the B cells and other immune cells that are present, even if they are present in lower numbers. Although Applicants disagree with the rejection, claim 28 has been amended to limit the definition of an immune system deficiency. The amendment should be sufficient to address this issue.

In the prior Office Action it was stated that the treatment and prevention of parasitic infection, such as malarial infection, is unpredictable because the parasite hides within a cell. In response Applicants presented papers by Gramzinski et al (Infect and Immunity v. 69, March 2001, p. 1643) and Jeamwattanalert et al (Clin Vaccine Immunol. 2007 Apr;14(4):342-7) that describe the use of CpG ODN in parasitic disease. The papers were not considered persuasive by the Patent

Office because the claims don't recite the exact oligonucleotide used in the papers. The papers were cited to show the beneficial effects of CpG oligonucleotides in a parasitic infection. It is also argued that mice models are not acceptable for studying CpG oligonucleotides. However, Applicants disagree. Numerous scientific articles have been published on the use of CpG oligonucleotides in animal models including mice. The authors of the 2 cited manuscripts published their findings in peer reviewed manuscripts. Thus, the scientific community must find mouse models of CpG oligonucleotides to provide acceptable teachings. Although Applicants disagree with the rejection, claim 28 has been amended to limit the definition of an immune system deficiency. The amendment should be sufficient to address this issue.

In response to the prior Office Action Applicants presented a 2007 review article by Krieg (J Clin Investigation, 2007, v 117, p. 1184) describing studies including human clinical trials using CpG in cancer and Sfondrini et al (FASEB 2002 v. 16, p. 1759) describing the prevention of spontaneous mammary adenocarcinoma in mice by CpG oligonucleotides. In response it is stated that Sfondrini et al do not disclose the instant CpG oligonucleotides. Applicants disagree. The oligonucleotide used in Sfondrini et al is referred to as ODN 1668 and includes a TGACGTT, one of the oligonucleotides claimed. Krieg is dismissed as showing the use of CpG as adjuvants for cancer vaccines and not being administered alone. Actually the reference shows CpG oligonucleotides being used in combination with vaccines as well as with chemotherapies and other therapies. The studies being described are human clinical trials The claims encompass the use of CpG oligonucleotides alone or in combination with other therapies. The data described in Krieg is presented to rebut the assertion that CpG oligonucleotides are not useful in the treatment of cancer and as such should be considered.

Double Patenting Rejection

Claims 28, 31-33, 35, 37, 39, 40, 42 and 43-47 have been rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claim 36 of copending Application No. 10/787,737. It is requested that the provisional rejection be held in abeyance until an indication of allowable subject matter is received.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. C1039.70083US06.

Dated: July 18, 2008

Respectfully submitted,

By _____

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